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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,647	10/08/2003	Jonathan D. Bloom	03127.000500.	8261
5514	7590	08/29/2007		EXAMINER
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				VALENROD, YEVGENY
			ART UNIT	PAPER NUMBER
			1621	
				MAIL DATE
				DELIVERY MODE
			08/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/682,647	BLOOM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yevgeny Valenrod	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 June 2007.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 1-10, 15 and 16 is/are allowed.  
 6) Claim(s) 11-14 and 17-18 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 11, 12, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al (J. Med. Chem. 2001 44 3187). On page 3188 column 2 structure 17, Wright teaches 2-{[N-(3-bromophenyl)glycyl]amino}benzoic acid which is found in the generic structure of claims 11, and 17 and is listed in claim 12. On page 3192, paragraph 3 (titled step 2), lines 7-12, Wright describe a method of preparing compound 17. They describe that after the reaction to form compound 17 is complete the mixture is extracted with dichloromethane and the aqueous phase is treated to recover the product. The product is recovered from the aqueous phase. Hence, before the recovery, compound 17 was in water, which is a pharmaceutically acceptable carrier. Limitations of instant claims directed to treatment of hepatitis represent an intended use and do not further limit the composition.

### **Applicants' remarks**

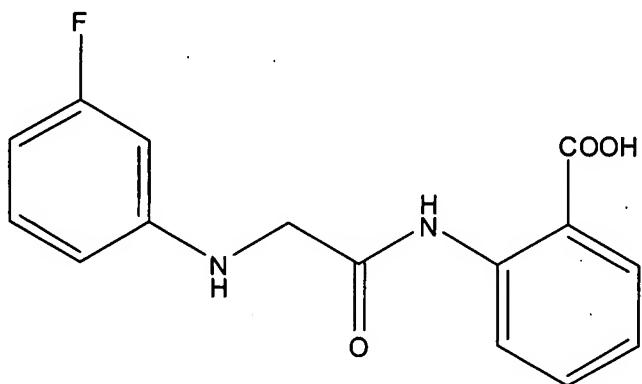
Applicant argues that the aqueous phase from which compound 17 is recovered does not necessarily contain only water. Other reagents are used in the process

leading to the recovery of 17 and some or all of them may be present in the aqueous phase, and some or all of them may not be suitable to be present in a pharmaceutically acceptable carrier.

Examiner's response

Examiner's position is that it is the burden of the applicant to provide evidence that the aqueous phase from which compound 17 is obtained contains reagents that are not suitable for a pharmaceutical composition. Absent such evidence, Wright anticipates claims 11, 12 and 17.

2. Claims 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bierer et al (US 5,741,926; from now on Bierer). In column 11, lines 42-43 Bierer discloses compound AC:



The compounds described by Bierer are described as pharmaceutical compositions (column 12, lines 23-28). Limitations of instant claims directed to

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treatment of hepatitis represent an intended use and do not further limit the composition.

***Rejection 35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bierer et al (US 5,741,926).

The instant application claims pharmaceutical compositions comprising compounds as described by formulas of independent claims 11 or 17, and their dependent claims 12-13 and 18.

*Scope of prior art*

Bierer et al. teach a general structure of Formula III that encompasses the compounds included in claims 11-14, 17 and 18 of the instant application.

*Ascertaining the difference between prior art and the instant application*

Although the structure of formula III taught by Bierer et al. encompasses the specific compounds of the instant application, it does not specifically list the same compounds as are recited in claims 12-13 and claim 18.

***Obviousness***

The generic structure of formula III teaches the instant claims with sufficient particularity that the compounds of the instant invention would have been *prima facie* obvious. The said particularity arises from structural similarities such as the 2-(((phenyl)amino)acetyl)aminobenzoic acid structural core and the optional multiple substitutions with various halogens which are present in the specific examples provided by Bierer et al (see column, 11 line 40 – column 12 line 16). One of ordinary skill in the arts would have been motivated to prepare the compositions claimed in the instant claims 11-14, 17 and 18 with an expectation that the said compositions will be useful as antihyperglycemic agents.

***Declaration under 37 C.F.R. 1.132***

The declaration filed by the applicant is not sufficient to overcome the rejections under 35 USC 102(b).

***Conclusion***

Claims 1-10 and 15-16 are allowed.

Claims 11-14 and 17-18 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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